UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAY 20 2010

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 6,635,618. The application was filed on October 15, 2009, under 35 U.S.C. § 156. Please note that Applicant has also applied for extension of U.S. Patent No. 7,208,471 (your docket no. FDA-E-2010-0024) and U.S. Patent No. 6,872,701 (your docket no. FDA-E-2010-0023) based on the same regulatory review period, i.e., NDA No. 22-110, pursuant to the provisions of 37 C.F.R. § 1.785.

The patent claims the human drug product VIBATIV®, a method of manufacturing VIBATIV® and a method of using VIBATIV®. VIBATIV® was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Jeffrey Hagenah
Patent Department
Theravance, Inc.
901 Gateway Blvd.
South San Francisco, CA 94080

RE: VIBATIV® (televancin hydrochloride)
Docket No.: FDA-2010-E-0022